

REMARKS

This is in response to the Official Action of September 9, 2003. Reconsideration in light of the remarks below is respectfully requested.

Election/restriction. In response to the requirement for restriction, the provisional election of Group I (claims 1-10) is hereby affirmed. Claims 11-46 have been cancelled herein, without prejudice to the filing of a divisional application thereon.

Priority. In response to the remarks concerning priority, the specification is amended above to recite a reference to the prior application in the first sentence of the specification. Entry thereof is respectfully requested.

Sequence rules. In response to the request for compliance with the Sequence Rules, the specification has been amended above to enter SEQ ID NO s, and a sequence listing and statement in support thereof is submitted concurrently herewith.

Enablement rejection. Claims 1-10 stand rejected as lacking enablement under the first paragraph of 35 USC 112. Reconsideration in light of the remarks set forth below is respectfully requested.

First, the claims have been clarified in light of the amendment made to respond to the indefiniteness rejection, as discussed below.

Second, claim 1 has been directed to a particular class of proliferative disease, support for which is found in the specification at page 9 line 32 through page 10 line 5. These are "the group consisting of breast cancer, melanoma, lung cancer, colon cancer, leukemia, soft tissue and bone sarcomas, neuroendocrine tumors, squamous carcinomas, and adenocarcinomas."

Third, applicants respectfully submit that cell lines are in fact a sufficient model for cancer risk in the context of the claimed invention. The CLN3 sequence is highly conserved across species. CLN3 has been shown to be elevated in mouse melanoma cells as shown in Figure 2 of Rylova et al., 2002, of record (which publication represents the work of the instant inventors). CLN3 is elevated in a variety of human cancer cell lines, including neuroblastoma, glioblastoma, prostate, ovarian, breast, melanoma, and pancreas cell lines, as shown in Figure 1 of Rylova et al. Finally, the blocking of CLN3 expression in prostate

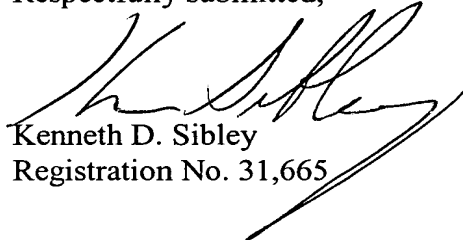
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cancer cells has been shown to increase apoptosis as shown in Figure 9 of Rylova et al.

In view of the foregoing, it is respectfully submitted that the claims of record satisfy the enablement requirement of 35 USC 112, first paragraph, and respectfully submitted that this rejection should be withdrawn.

35 USC 112 Second Paragraph. Claims 1-10 stand rejected under 35 USC 112, second paragraph, for various informalities therein. Claim 1 has been amended to make the preamble more consistent with the conclusion therein. Claim 10 has been amended to correct "said patient" to read "said subject". It is respectfully submitted that these amendments place the claims in a form that satisfies the second paragraph of 35 USC 112, and respectfully submitted that this rejection should be withdrawn.

Respectfully submitted,



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